Aerotel Medical Systems (1998) Ltd.
Special 510(k)
Heart 2006 Cardiac Event Recorder

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements Regulation par. 807.92, effective March 14, 1995.

1. Submitter

Name: Aerotel Medical Systems (1998) Ltd
Address: 5 Hazoref St., Holon 58856, Israel
Telephone Number: 972-3-5596111
Contact person: Dr. George Myers, 210-787- 1703
Date prepared: March 7, 2000

2. Device

Proprietary name: Heart 2006
Common Name: Electrocardiograph Event Recorder and Telephonic Transmitter
Classification Name: Transmitters and Receivers, electrocardiograph, telephone

The Heart 2006 is a battery-powered ECG event recorder and transmitter that is capable of storing an electrocardiogram and transmitting it by means of a telephone to a central receiving station. It records a portion of the ECG both before and after a "Record" button is depressed.

3. Predicate Device

Heart 2005, K000775, manufactured by Aerotel Medical Systems (1998) Ltd..

4. Description

The H2006 is a battery powered ECG Event Recorder and Transmitter which is intended to be used by the patient to record portions of a patient's electrocardiogram (ECG) and to send it to a receiving center such as Aerotel's Heartline Receiving Station (FDA # K022073) or equivalent. It records portions of the ECG both before and after the Record button is depressed.

5. Intended Use

The **Heart 2006 is a** long-term portable electrocardiogram monitor intended to be used for long-term cardiac out-patient management. The unit records a period of electrocardiogram whenever the patient feels symptoms, as indicated to him by a

physician, and presses a button on the unit. The electrocardiograms are then sent to the physician by telephone.

The unit is indicated whenever it is desired to have electrocardiograms of a symptomatic patient at the time of the symptoms. There are no known contraindications.

6. Comparison

The Heart 2006 is a modified version of the predicate device. It has basically the same electrical and mechanical characteristics, and the use of the two devices by the patient is equivalent.

7. Performance Data

(1) Non-clinical tests

The modifications were validated by repeating IEC 601-1 and IEC 601-1-2 tests (electrical safety and electromagnetic compatibility) and the electrical characteristic tests of standard EC38.

(2) Clinical Tests

No clinical tests were performed.

8. Conclusion

The conclusion drawn from these tests is that the Heart 2006 is equivalent in safety and efficacy to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 3 2003

Aerotel Medical Systems (1998) Ltd.
c/o George H. Myers, Sc.D.
President
Medsys Inc.
377 Route 17 South
Hasbrouck Heights, NJ 07604

Re: K032736
Trade Name: Heart 2006
Regulation Number: 21 CFR 870.2920
Regulation Name: Telephone Electrocardiograph Transmitter and Receiver
Regulatory Class: Class II (two)
Product Code: DXH
Dated: September 2, 2003
Received: September 4, 2003

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K032736

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510(k) Number (if known):_____

Indications for Use Form

Device Name: Heart 2005

Indications for Use:

The **Heart 2006 is a** long-term portable electrocardiogram monitor intended to be used for long-term cardiac out-patient management. The unit records a period of electrocardiogram whenever the patient feels symptoms, as indicated to him by a physician, and presses a button on the unit. The electrocardiograms are then sent to the physician by telephone.

The unit is indicated whenever it is desired to have electrocardiograms of a symptomatic patient at the time of the symptoms. There are no known contraindications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the-Counter Use**_____
(Per 21 CFR 810.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K032736